



U. S. Department of Justice
Drug Enforcement Administration

SL

Washington, D.C. 20537

JUL 23 1998

Chris Zimmerman, Director
Regulatory Compliance and
Security Services
Bergen Brunswig Corporation
4000 Metropolitan Drive
Orange, CA 92868

Dear Mr. Zimmerman:

This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal regulation. DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion which is not only useful overall, but is also responsive to the needs of individual DEA offices.

We appreciate the efforts you have undertaken to develop this improved system and apologize for the lengthy approval process. It did not seem appropriate to grant this approval prior to the conclusion of the Suspicious Order Task Force formed as a result of the Methamphetamine Control Act. Thank you for your patience in this matter.

If you have any questions, please do not hesitate to call at (202) 307-7297.

Sincerely,

Patricia M. Good
Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

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AM-WV-00781



Via Certified Mail

4000 Metropolitan Drive, Orange, CA 92868 (714) 385-4000

May 20, 1998

Ms. Patricia M. Good
Chief, Liaison and Policy Section
Drug Enforcement Administration
United States Department of Justice
Washington, DC 20537

Dear Ms. Good,

The purpose of this letter is to serve as a follow up to previous written correspondence (copy enclosed) and telephone conversations Bergen Brunswig Drug Company (BBDC) has had with the Drug Enforcement Administration (DEA) pertaining to BBDC's newly developed system to monitor and report customer orders of controlled substances (and now Listed Chemicals) which fit the suspicious order criteria outlined in 21 CFR § 1301.74 (b).

The system is clearly described in the enclosed September 30, 1996 correspondence and per instruction from Tom Gitchel, BBDC began beta-testing the new suspicious order reporting system with the DEA Los Angeles (LA) Field Office in March 1997. Our BBDC Valencia Division began the new suspicious order reporting to the LA-DEA Office on March 1, 1997; BBDC Corona Division began reporting to the Riverside DEA Office on April 1, 1997; BBDC Hawaii began reporting to the Hawaii-DEA Office on May 1, 1997; and BBDC Orlando began reporting to Tampa DEA Office on June 1, 1997. All BBDC test divisions are currently reporting suspicious orders to DEA, via the auto-fax function of the new reporting system.

We have had several conversations/meetings with Ms. Betsy Willis, Los Angeles DEA Diversion Program Manager, Ms. Valencia Abrams, San Diego DEA Program Manager (former Los Angeles Diversion Group Supervisor), Mr. Thomas Cox, DEA Riverside Diversion Group Supervisor, and Mr. Arthur Fierman-Rentas, DEA Tampa Diversion Group Supervisor. All DEA personnel currently involved with the beta-test program have been very pleased, and Ms. Willis has given BBDC permission not to submit our Monthly ARCOS Suspicious Order Report (Variance Report) to DEA for the BBDC Corona, Valencia, and Hawaii Divisions. (Correspondence enclosed)

The Methamphetamine Control Act requires distributors to report suspicious orders of Listed Chemicals to DEA, 21 CFR 1310.05 (a)(1). BBDC's new suspicious order reporting system will not only apply to controlled substances, but will also include Listed Chemicals. In California, BBDC has been utilizing the new reporting system to adhere to state requirements to report suspicious orders of ephedrine and pseudoephedrine to the California Bureau of Narcotics and Dangerous Drugs.

BBDC has already made several changes to our proposed new reporting system at the direction of the DEA field offices in which it is being tested. It has been an extremely positive experience working closely with DEA to develop a suspicious order reporting system that benefits both the wholesaler and DEA. I wanted to also acknowledge the efforts of Ms. Willis with regard to the successful beta-testing of the new suspicious order reporting system. Ms. Willis's cooperation and insight made the transition from the traditional reporting system to the new reporting system seem effortless.

Patricia M. Good - DEA
May 20, 1998
Page 2

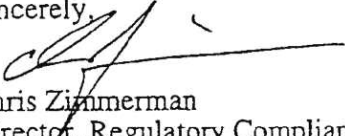
We are confident that this new suspicious order reporting system will greatly benefit both BBDC and DEA, and are ready to begin implementation of the new suspicious reporting system nationwide. I believe that the new system will not only save both BBDC and DEA valuable time and resources, but will also provide DEA with a much better tool to detect diversion. BBDC is still very excited about this opportunity and would like to continue moving forward in the implementation of our new suspicious order reporting system.

BBDC has approached other DEA Field Offices regarding the implementation and beta-testing of our new suspicious order reporting system, however, those DEA Field Offices have indicated that they would not implement the new reporting system until they received direction from Washington D.C.

During our last conversation you indicated that you would be meeting with the Program Managers in March 1998, and BBDC's new suspicious order reporting system was one of the items you were going to discuss. I know you have been extremely busy over the past months and we have been unable to connect to discuss the possible implementation of BBDC's new suspicious order reporting system. BBDC is ready to implement the new system nationwide and we are requesting approval from your department to begin implementing the new suspicious order reporting system at other DEA Field Locations.

BBDC is committed to the success of this new system. If DEA has any questions or needs additional information before approval can be granted, BBDC would welcome a meeting with DEA in either Washington D.C. or our corporate headquarters in Orange, California. I am looking forward to your response, if you have any questions or need any additional information, please contact me at (714) 385-4267.

Sincerely,



Chris Zimmerman
Director, Regulatory Compliance
and Security Services

66



Bergen Brunswig Corporation

Via Certified Mail

4070 Metropolitan Drive Orange, CA 92668 (714) 385-4000

December 30, 1997

Mr. G. Thomas Gitchel
Chief, Liaison and Policy Section
Drug Enforcement Administration
United States Department of Justice
Washington, DC 20537

Dear Mr. Gitchel,

This letter serves as a follow up to previous written correspondence (copy enclosed) and telephone conversations Bergen Brunswig Drug Company (BBDC) has had with the Drug Enforcement Administration (DEA) pertaining to BBDC's newly developed system to monitor and report customer orders of controlled substances which fit the suspicious order criteria outlined in 21 CFR § 1301.74 (b).

The system is clearly described in the enclosed September 30, 1996 correspondence. Per your instruction, BBDC began "beta-testing" the new suspicious order reporting system with the DEA Los Angeles (LA) Field Office in March 1997. Our BBDC Valencia Division began the new suspicious order reporting to the LA-DEA Office on March 1, 1997; BBDC Corona Division began the new reporting to the Riverside DEA Office on April 1, 1997; BBDC Hawaii began this new reporting to LA-DEA Office on May 1, 1997; and BBDC Orlando began the new reporting to the Tampa DEA Office on June 1, 1997. All BBDC test divisions are currently reporting suspicious orders to DEA, via the automated-fax function of the new reporting system.

We have had several conversations/meetings with Ms. Betsy Willis, DEA Diversion Program Manager, Ms. Valencia Abrams, DEA Los Angeles Diversion Group Supervisor, Mr. Thomas Cox, DEA Riverside Diversion Group Supervisor, and Mr. Arthur Fierman-Rentas, DEA Tampa Diversion Group Supervisor. All DEA personnel currently involved with the beta-test program have been very pleased, and Ms. Willis has given BBDC permission to discontinue the submission of our monthly ARCOS Suspicious Order Report (Variance Report) to DEA for the BBDC Corona, Valencia, and Hawaii Divisions. (Correspondence enclosed)

The Methamphetamine Control Act requires distributors to report suspicious orders of Listed Chemicals to DEA. BBDC's new suspicious order reporting system will not only apply to controlled substances, but will also include Listed Chemicals. In California, BBDC will begin utilizing the new reporting system to adhere to state requirements to report suspicious orders of ephedrine and pseudoephedrine to the Bureau of Narcotics and Dangerous Drugs in January 1998.

BBDC has approached other DEA Field Offices regarding the implementation and beta-testing of our new suspicious order reporting system, however, those DEA Field Offices have indicated that they would not implement the new reporting system until they received direction from Washington D.C.

G. Thomas Gitchel - DEA
December 30, 1997
Page 2

BBDC has already made several changes to our proposed new reporting system at the direction of the DEA field offices in whose jurisdictions it is being tested. It has been an extremely positive experience working closely with DEA to develop a suspicious order reporting system that benefits both the wholesaler and DEA. I would like to acknowledge the efforts of Ms. Willis with regard to the successful beta-testing of the new suspicious order reporting system. Ms. Willis's cooperation and insight made the transition from the traditional reporting system to the new reporting system seem effortless.

We are confident that this new suspicious order reporting system will benefit both BBDC and DEA, and are optimistic that we will be able to begin implementation of the new suspicious reporting system nation wide. I believe that the new system will not only save both BBDC and DEA valuable time and resources, but will also provide DEA with more useful tool with which to detect diversion. BBDC is excited about this opportunity and would like to continue moving forward with the implementation of our new suspicious order reporting system.

During our last conversation you indicated that you would be meeting with the Program Managers and one of the items you would be to discussing was BBDC's new suspicious order reporting system. I know you have been extremely busy over the past couple months and we have been unable to connect to discuss the possible implementation of BBDC's new suspicious order reporting system. BBDC is ready to implement the new system nationwide and we are requesting approval from your department to begin implementing the new suspicious order reporting system at other DEA Field Locations.

Tom, BBDC is committed to the success of this new system. If DEA has any questions or needs additional information before approval can be granted, BBDC would welcome a meeting with DEA in either Washington D.C. or our corporate headquarters in Orange, California. I am looking forward to your response, if you have any questions, please contact me at (714) 385-4267.

Sincerely,



Chris Zimmerman
Director, Regulatory Compliance
and Security Services



U. S. Department of Justice

Drug Enforcement Administration

Los Angeles Field Division
255 East Temple Street, 20th Floor
Los Angeles, California 90012

October 3, 1997

Mr. Chris Zimmerman
Bergen Brunswig Corporation
4000 Metropolitan Drive
Orange, CA. 92668

Dear Mr. Zimmerman:

This letter is follow up to our conversations concerning Bergen Brunswig Corporation's continued filing of the excessive purchase monthly variance report. As discussed, I have contacted the Drug Enforcement Administration (DEA), Office of Diversion Control, Liaison and Policy Section, concerning the legal obligation for Bergen Brunswig to file this report. I have received concurrence that at those Bergen Brunswig facilities which utilize your new automated excess purchase identification and reporting program, there is no legal requirement for continued filing of the monthly variance report.

Therefore, effective immediately, the Bergen Brunswig distribution centers located in Valencia, California, Corona, California, and Honolulu, Hawaii may cease submitting the monthly variance report to DEA. This authorization is contingent upon continued reporting via the automated identification program. Any changes in these reporting procedures will require further approval by this office.

This authorization is for the above mentioned Bergen Brunswig facilities within the jurisdiction of the DEA Los Angeles Field Division only. Authorization for discontinuing the monthly variance report at other Bergen Brunswig facilities must be obtained either from the Liaison and Policy Section or the responsible DEA field office.

If you should have any questions on this matter, please do not hesitate to contact me at (213) 894-8267.

Sincerely,

A handwritten signature in cursive script, reading "Elizabeth A. Willis", is written above the typed name.

Elizabeth A. Willis
Diversion Program Manager



U.S. Department of Justice
Drug Enforcement Administration

RECEIVED

NOV 04 1996

CORPORATE SECURITY

Washington, D.C. 20537

OCT 29 1996

Mr. Chris Zimmerman
Manager, Corporate Security
Bergen Brunswig Corporation
4000 Metropolitan Drive
Orange, California 92668

Dear Mr. Zimmerman:

Reference is made to your recent letter in which you requested that Bergen Brunswig be permitted to replace its current telephonic reporting of suspicious orders with a daily report transmitted by facsimile.

We have reviewed your proposal and feel that it could be a viable alternative to the current system. It is our understanding that a computer program has been created that can compare a customer's controlled substance orders to an average of the customer's orders for the prior four months. Customers' orders that exceed their four month average order history by an as yet unspecified percentage would be shown on a summary report that would be sent to the appropriate Drug Enforcement Administration (DEA) field office on a daily basis. As proposed, the summary report would include the customer's name, address and DEA number; a description of the item ordered; the NDC number; date ordered; active ingredient volume ordered and shipped; and the customer's "allowance" or average order.

We note that, unlike the program that generates Bergen Brunswig's monthly suspicious order report, the new program will compare the customer's order to his or her previous orders rather than to orders placed by other customers. It is therefore requested that each DEA office continue to be provided with the monthly reports in addition to the daily facsimile reports. It would also be helpful to our investigators if the quantity of drugs ordered were expressed in dosage units rather than by the weight of the active ingredient.

We agree that it would be prudent to test this new program before instituting it nationwide and concur with your suggestion to use the DEA Los Angeles Division office for the beta test. We would

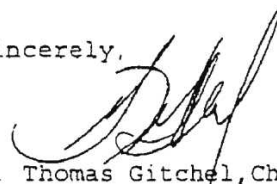
Mr. Chris Zimmerman

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appreciate it if you would postpone starting the testing until after February 1, 1997, as Ms. Betsy Willis, who has been selected for the Diversion Program Manager position in the Los Angeles Field Division, will not be reporting for duty until the end of January. It is suggested that you contact Ms. Willis after January 20, 1997 to discuss this matter further. Ms. Willis may be reached at (213) 894-4015 after that date.

We look forward to working with you on this new project which we, too, hope will lead to a more efficient suspicious order reporting system. If you have any questions please let me know.

Sincerely,



G. Thomas Gitchel, Chief
Liaison and Policy Section
Office of Diversion Control

Via Certified Mail



Bergen Brunswig Corporation

4000 Metropolitan Drive, Orange, CA 92668 (714) 385-4000

September 30, 1996

Mr. G. Thomas Gitchel
Chief, Liaison and Policy Section
Drug Enforcement Administration
United States Department of Justice
Washington, DC 20537

Dear Mr. Gitchel,

The purpose of this letter is to introduce the Drug Enforcement Administration (DEA) to an innovative new system under development by Bergen Brunswig Drug Company (BBDC) to monitor and report customer orders of controlled substances which fit the suspicious order criteria outlined in 21 CFR § 1301.74 (b).

By way of background, as you know BBDC participated in the development of a model Excessive Purchase Report now in use by many distributor registrants. As used by BBDC, the Excessive Purchase Report lists total customer purchases for the reported month which exceed pre-determined multiples of the average monthly purchases of BBDC's total customer base. The program identifies purchases by individual DEA Drug Code and reads BBDC's sales files to calculate averages to be used as reporting criteria. The printed report (actually a series of reports) separates pharmacy registrants and hospital registrants, and further separates purchases by ARCOS class substances and non-ARCOS class substances within the respective pharmacy and hospital reports. This report is produced in hard-copy form monthly and is sent via certified mail to each DEA Field Office having responsibility for the reporting BBDC locations.

While feedback from different DEA users over the years has generally confirmed our belief that this report, standing alone, is a useful law enforcement tool, BBDC's suspicious order compliance program also involves the telephonic reporting of customer orders to DEA. In an average year, BBDC logs over twelve thousand (12,000) telephone calls to DEA Field Offices nationwide to orally report customer orders of controlled substances which it believes could fit the suspicious order criteria set forth in § 1301.74 (b). In nearly every instance, the telephonic contacts are made to report orders which later appear on the month-end Excessive Purchase Report sent to DEA.

As you may imagine given the sheer number of BBDC's contacts, DEA Field Office response to the frequency and manner of BBDC's contacts has been varied. Some Field Offices have insisted that BBDC not telephonically report suspicious orders at all, but rather

G. Thomas Gitchel - DEA
 September 30, 1996
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to mail or fax copies of the order documents, 222 Forms or invoices to them instead. Some offices have diplomatically attempted to offer guidance as to the types of orders that their office would deem to be "reportable" in an effort to limit the number of telephone contacts. These telephone contacts are inefficient, burdensome and costly both for BBDC and DEA, as the telephone calls tie up DEA Investigator time and consume precious administrative resources.

I could appreciate DEA's belief that 12,000 BBDC telephone calls per year may be "over doing it," if not for the fact that the regulations clearly place the responsibility solely on the registrant to disclose any orders which fit the suspicious order criteria, and it has always been BBDC's position to adopt a conservative and thorough approach on matters involving controlled substance regulatory compliance.

In June 1995, Steve Harrold, BBDC Director, Corporate Security, attended the DEA-Industry Conference held in Naples, Florida. At this conference, in the Workshop entitled "Improving Utilization of Existing Technology to Meet DEA Requirements" led by Michael Moy, Mr. Harrold reported on the issue of telephonic suspicious order reporting and the consequent requests BBDC had received from various DEA Field Offices to limit suspicious order reports by telephone or to report orders in other ways (e.g. sending copies of orders by U.S. Mail, Fax, etc.). It was Mr. Harrold's impression that DEA would be amenable to exploring the concept of electronic transmission of suspicious orders.

Against this backdrop, BBDC set to work on the development of a suspicious order reporting program that would provide better quality information to DEA in a more efficient manner.

Our plan involves the creation of a computer program that compares a customer's controlled substance orders (expressed in metric units of the active ingredient) against a standard representing an average of the customer's prior four months of orders. Customer's whose orders exceed by a specified percentage their prior four month average order history would be printed on a summary report. BBDC's mainframe computer in Orange, California would automatically fax this report simultaneously to each respective DEA Field Office daily in the early AM hours after the distribution center has completed order processing activities. When DEA offices open each day, the summary report would be waiting for their review. DEA offices could also elect to receive a month-end version of this report via U.S. Mail. The summary report would show the customer name, address, DEA Number, Item Description, NDC Number, Order Date, Active Ingredient Volume Ordered, Active Ingredient Shipped and Customer "Allowance" (i.e. average of customers' prior four months orders).

While the current month-end report compares a customer's purchases against an average of calendar month sales to all like customers, the proposed report would compare a customer's daily orders against that customer's prior orders. This analysis would theoretically spot a customer who orders a singularly large amount of controlled substances. The current month-end report would continue to look at the customer's purchases in light of the entire customer base.


G. Thomas Gitchel - DEA
September 30, 1996
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Our intent is to receive DEA's permission to replace our current manner of daily suspicious order reporting (e.g. U.S. Mail; Telephone Calls) with this daily electronic facsimile report. We would like to have DEA input on the final product because DEA will be the primary users. One suggestion would be to coordinate with one of your Field Offices, perhaps the Los Angeles Office, to meet with our project development team. Your field office could beta test the report and provide us with input on aesthetics and content. There are some key questions that DEA would need to provide input on before the report is finalized. One question would be the assignment of the percentage value that a customer's order would have to exceed before that order would appear on the report. This value would directly impact the size of the report. Working with DEA's input, we hopefully will identify the optimum percentage value that will yield DEA the highest quality information without sacrificing administrative cost and efficiency. Once the Field Office test is concluded and the recommendations incorporated into the final product, then we can coordinate with your office to introduce the report to the entire DEA system.

Tom, we are excited about this opportunity to make constructive changes in our suspicious order reporting program. By working in a partnership with your office, we can perhaps lead the way to developing a new system that everyone feels good about.

I will schedule a call to your office in about two weeks to follow-up on this letter and to speak with you about how we can move forward.

Sincerely,



Chris Zimmerman
Manager, Corporate Security

07 5/24/98 HC

Is your RETURN ADDRESS completed on the reverse side?

SENDER:

- Complete items 1 and/or 2 for additional services.
- Complete items 3, 4a, and 4b.
- Print your name and address on the reverse of this form so that we can return this card to you.
- Attach this form to the front of the mailpiece, or on the back if space does not permit.
- Write "Return Receipt Requested" on the mailpiece below the article number.
- The Return Receipt will show to whom the article was delivered and the date delivered.

I also wish to receive the following services (for an extra fee):

- ☐ Addressee's Address
- ☐ Restricted Delivery

Consult postmaster for fee.

3. Article Addressed to:

Ms. Patricia Good
DEA
U.S. Dept of Justice
Washington DC 20537

4a. Article Number

P413274515

4b. Service Type

☐ Registered ☒ Certified
☐ Express Mail ☐ Insured
☐ Return Receipt for Merchandise ☐ COD

7. Date of Delivery

5. Received By: (Print Name)

6. Signature: (Addressee or Agent)

X [Signature]

8. Addressee's Address (Only if requested and fee is paid)

PS Form 3811, December 1994 102595-97-5-0179 Domestic Return Receipt

Thank you for using Return Receipt Service.